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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/634,642
Filing Date: August 04, 2003
Appellant(s): PETERS ET AL.

James W. Geriak
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 26, 2007 appealing from the Office action mailed August 18, 2006 and vacates the previous Examiner Answer on February 22, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

NEW GROUND(S) OF REJECTION

The new grounds of rejection were previously made of record on April 11, 2006.

As of May 23, 2006, the claims were amended to include a "*non-expandable* shell". The inclusion of the limitation caused the new rejection necessitated by amendment on August 18, 2006. However, the removal of "*non-expandable*"" enabled the claims to be rejected under the previous grounds of rejection recited in the Office Action dated April 11, 2006 (prior to the inclusion of "non-expandable" shell). This was indicated to the Appellant in the Advisory Action dated October 20, 2006.

Thus the new grounds of rejection, previously made on April 11, 2006, are included herein under (9) Grounds of Rejection.

(7) Claims Appendix

A substantially correct copy of appealed claims 1-17 and 19-32 appears on page 12 of the Appendix to the appellant's brief. The minor errors are as follows: the omission of claim 18. Although claim 18 was cancelled there should be some indication in the Appendix.

(8) Evidence Relied Upon

5820542	Dobak, III et al.
5827171	Dobak, III et al.
6210318	Lederman

(9) Grounds of Rejection

NEW GROUND(S) OF REJECTION

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-11, 13-14, 16-17, 23-26 and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Dobak, III et al. (US 5,827,171). Dobak, III et al. discloses an intravascular circulatory assist device with an outer balloon, inner balloon and a stent.

As to claims 1-2, 7-8 and 25, figure 1 depicts catheter 12 with the inner balloon 14 is the balloon or chamber and the outer balloon is a protective balloon 18, which acts as a shell. The stent 20 is disposed within balloon 16 and is an expandable frame. Thus it is balloon or chamber expandable.

As to claim 1, it has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

Also, the functional language and introductory statement of intended use of claim 1 has been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Dobak, III et al. utilizes a balloon and a shell as claimed by the Appellant, Dobak, III et al. is therefore capable of using the shell to provide location and direction to the balloon during inflation and deflation. In addition nothing prevents Dobak, III et al. from employing the shell for location and direction for a specific pattern of inflation and deflation. Therefore, the balloon is capable of being used with a shell to modify inflation and deflation.

As to claims 3, 24 and 29, since the balloon 14 is located on the inside of the stent 20, the balloon is attached to the inner wall of the frame. Furthermore, since the balloon is disposed within the stent in the same system, the balloon and stent are necessarily coupled.

As to claim 4, figure 3 displays a self-expanding stent 20.

As to claims 5-6, "the stent 20 used in this embodiment (figure 2) is the thermally expanding stent 20 made of a material such as nitinol"(col. 7, lines 37-38). Nitinol is a nickel-titanium alloy, which is a shape memory alloy and is also a spring material.

As to claim 9, "the stent 20 is an expandable, substantially cylindrical, lattice of elongated elements of plastic or metal. It can be similar to cardiovascular stents known in the art"(col. 5, lines 38-39). The examiner considers the lattice of elongated elements to be a lattice of wires.

As to claim 10, "the balloons 14, 16, 18 are made of a flexible material which can expand up to a desired size, or diameter, after which the material essentially does not expand further, even if the pressure inside the balloon is increased further. Such materials, and the processes used in their fabrication, are widely used in the manufacture of balloons for angioplasty"(col. 5, lines 16-22). Since the balloons cover the stents, the examiner considers the balloons to be comprised of a fabric and thus the stents are covered with a fabric.

As to claim 11, the balloon forms a coating around the stent.

As to claim 13, since the balloon is located inside the lumen of the stent, the balloon extends substantially around the full circumference of the frame lumen.

As to claim 16-17, "when the outer balloon 16 is in the expanded state, a control space 26 is created between the outer balloon 16 and the inner balloon 14. This control space 26 is repetitively evacuated and pressurized with a control fluid, to achieve the expansion and collapse of the inner balloon 14"(col. 6, lines 31-35). As seen in figure 1 there is a control fluid pressure source P is connected to the balloon chamber(s) via the conducting tube (depicted as "A"). This control fluid affects the control space 26 to facilitate a pumping action and as such the balloon or chamber (balloon 14) is connected to the control fluid pressure source.

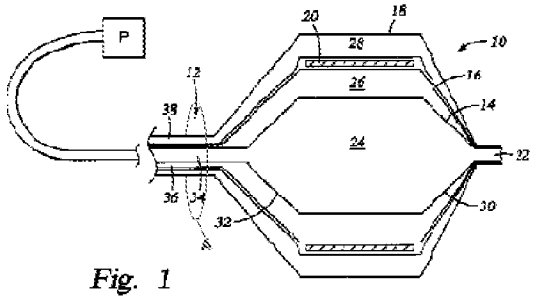

Fig. 1

As to claim 23, the Appellant discloses the balloon or chamber expands away from the wall of the shell. However, as explained above, the examiner is unsure which wall the balloon or chamber is expanding towards and which wall it is expanding away from. Therefore, in regards to the unclear recitation, the top of the balloon or chamber of Dobak, III et al. expands towards the top part of the shell wall and expanding away from the other part, bottom, of the shell wall. Therefore, Dobak, III et al. does in fact expand away from the shell. Furthermore, the inner balloon is positioned adjacent to the wall when it is in a contracted state.

As to claim 26, there is necessarily an aperture in an artery wall in order to place the catheter delivery system into the vasculature.

As to claim 28, the circulatory assist device has a port 22 for the flow of blood or other vascular fluid. Therefore, blood would flow through the balloon and stent instead

of flowing over the surface of the shell or protective balloon 18. Furthermore, it has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

As to claim 30, the claim recites the limitation, a "shell having an arcuate cross-section, the interior surface of said balloon or chamber facing the concave surface of said shell". The shell, as seen in figure 1, has an interior concave surface and an arcuate cross-section.

2. Claims 1-17, 23-26 and 28-30 stand rejected and 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Dobak, III et al. (US 5,820,542). Dobak, III et al. discloses an intravascular circulatory assist device with an outer balloon, inner balloon and a stent.

As to claims 1-2, 7-8 and 25, figure 1 depicts catheter 12 with a pumping membrane 14 as the balloon or chamber and the protective membrane 18, which acts as a shell. The stent 20 is disposed within housing 16 and is an expandable frame. Thus it is balloon or chamber expandable.

As to claim 1, it has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

Also, the functional language and introductory statement of intended use of claim 1 has been carefully considered but are not considered to impart any further structural

limitations over the prior art. Since Dobak, III et al. utilizes a balloon and a shell as claimed by the Appellant, Dobak, III et al. is therefore capable of using the shell to provide location and direction to the balloon during inflation and deflation. In addition nothing prevents Dobak, III et al. from employing the shell for location and direction for a specific pattern of inflation and deflation. Therefore, the balloon is capable of being used with a shell to modify inflation and deflation.

As to claims 3, 24 and 29, since the pumping membrane or balloon 14 is located on the inside of the stent 20, the balloon is attached to the inner wall of the frame. Furthermore, since the balloon is disposed within the stent in the same system, the balloon and stent are necessarily coupled.

As to claim 4, figure 3 displays a self-expanding stent 20.

As to claims 5-6, "the stent 20 used in this embodiment is the thermally expanding stent 20 made of a material such as nitinol"(col. 9, lines 18-19). Nitinol is a nickel-titanium alloy, which is a shape memory alloy and is also a spring material.

As to claim 9, "the stent 20 is an expandable, substantially cylindrical, lattice of elongated elements of plastic or metal. It can be similar to cardiovascular stents known in the art"(col. 7, lines 19-21). The examiner considers the lattice of elongated elements to be a lattice of wires.

As to claim 10, "the housing 16 and the membranes 14,18 can be made of a flexible material which can expand up to a desired size, or diameter, after which the material essentially does not expand further, even if the pressure inside the housing or membranes is increased further. Such materials, and the processes used in their

fabrication, are widely used in the manufacture of balloons for angioplasty"(col. 6-7, lines 64-67 and 1-3). Since the housing could consist of two laminated membranes with the stent disposed within them and the examiner considers the membranes to be comprised of a fabric, the stent as a result would be covered with a fabric.

As to claim 11, the balloon forms a coating around the stent.

As to claim 13, since the balloon is located inside the lumen of the stent, the balloon extends substantially around the full circumference of the frame lumen.

As to claim 16-17, "when the housing 16 is in the expanded state, a control chamber 26 is created between the housing 16 and the pumping membrane 14. This control chamber 26 is repetitively evacuated and pressurized with a control fluid, to achieve the expansion and collapse of the pumping membrane 14"(col. 8, lines 12-17). As seen in figure 1 there is a control fluid pressure source P is connected to the balloon chamber(s) via the conducting tube (depicted as "A"). This control fluid affects the control chamber 26 to facilitate a pumping action and as such the pumping membrane 14 is connected to the control fluid pressure source.

As to claim 23, the Appellant discloses the balloon or chamber expands away from the wall of the shell. However, as explained above, the examiner is unsure which wall the balloon or chamber is expanding towards and which wall it is expanding away from. Therefore, in regards to the unclear recitation, the top of the balloon or chamber of Dobak, III et al. expands towards the top part of the shell wall and expanding away from the other part, bottom, of the shell wall. Therefore, Dobak, III et al. does in fact expand

away from the shell. Furthermore, the inner balloon is positioned adjacent to the wall when it is in a contracted state.

As to claim 26, there necessarily has to be an aperture in an artery wall in order to place the catheter delivery system into the vasculature.

As to claim 28, the circulatory assist device has a port 22 for the flow of blood or other vascular fluid. Therefore, blood would flow through the balloon and stent instead of flowing over the surface of the shell or protective balloon 18. Furthermore, it has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

As to claim 30, the claim recites the limitation, a "shell having an arcuate cross-section, the interior surface of said balloon or chamber facing the concave surface of said shell". The shell, as seen in figure 1, has an interior concave surface and an arcuate cross-section.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 21-22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak, III et al. (US 5,827,171) or Dobak, III et al. (US 5,820,542). Dobak, III et al.

discloses the claimed invention except for the sternotomy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the placement of the assist device as taught by Dobak, III et al. with implantation by a sternotomy since it was known in the art that to implant medical devices into the patients chest cavity via a sternotomy. Furthermore, it is also well know in the art to modify a surgical procedure to yield the predictable results of meeting specific patient needs and surgical requirements.

As to claim 22, Dobak, III et al. discloses the claimed invention except for the aortotomy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the placement of the assist device as taught by Dobak, III et al. with connecting the device via a aortotomy since it was known in the art to insert a balloon into the thoracic aorta to augment blood flow, as taught by Dobak, III et al. '542. Furthermore, it is also well know in the art to modify a surgical procedure to yield the predictable results of meeting specific patient needs and surgical requirements

2. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak, III et al. (US 5,827,171) or Dobak, III et al. (US 5,820,542) in view of Lederman (US 6,210,318). Dobak, III et al. teaches the device substantially as claimed except for the gas inflating and deflating the pumping balloon. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the fluid as taught by Dobak, III et al. with the fluid, a gas, as taught by Lederman since both fluids can both employed to obtain predictable results of causing the inflation and deflation of the pumping balloon.

3. Claims 14 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak, III et al. (US 5,827,171) or Dobak, III et al. (US 5,820,542). Dobak, III et al. discloses the claimed invention but does not disclose expressly the balloon or chamber extending around only a portion of the circumference within the frame lumen. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the expansion of the balloon or chamber from the full circumference within the frame lumen as taught by Dobak, III et al., to an expansion that does not extend around the full circumference but only a portion, because Appellant has not disclosed that a partial expansion provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Appellant's invention to perform equally well with the expansion to the full circumference as taught by Dobak, III et al., since both the full and partial circumference expansion would both equally assist the heart as a pumping circulatory assist device.

Therefore, it would have been an obvious matter of design choice to modify the expansion of the balloon or chamber to obtain the invention as specified in the claim(s).

(10) Response to Argument

In regard to the Appellant's request to remove the present art of record in favor of the Freed patent (US 6,471,633), the examiner has considered the Freed, but maintains that both Dobak, III et al. (US 5,827,171) and Dobak, III et al. (US 5,820,542) are more relevant to the pending claims.

The Appellant argues that both Dobak, III et al. (US 5,827,171), hereafter referred to as Dobak '171, and Dobak, III et al. (US 5,820,542), hereafter referred to as

Dobak ‘542, do not discloses a shell. However, as previously indicated, the examiner considers the outer balloon 18 to function as a shell. Therefore, with respect to the present claims, both Dobak ‘171 and Dobak ‘542 disclose a shell.

Furthermore, the Appellant argues that the “shell is non-expandable”. In response to Appellant’s argument that the references fail to show certain features of Appellant’s invention, it is noted that the features upon which Appellant relies (i.e., the shell is non-expandable) are not recited in the pending claims. Therefore, since the arguments are not supported by the now pending claims, the arguments are irrelevant.

With regards to the Appellant’s arguments that the stent of Dobak ‘171 and Dobak ‘542 is not attached to the balloon or chamber, attention is drawn to figure 1 to display the balloon or chamber being attached to a portion of the frame.

The Appellant’s also argues that the stent can not be covered in fabric. However, the examiner again restates that since the housing around the stent could consist of two laminated membranes with the stent disposed within them, the examiner considers the membranes to be comprised of a fabric, and thus the stent would be covered with a fabric.

With regards to the Appellant's argument that neither Dobak ‘171 nor Dobak ‘542 disclose a balloon extending around the full circumference wherein there is substantially no space between the balloon and lumen of the stent. However, as depicted in figure 1, the balloon inflates around the full circumference of the stent and leaves substantially no space between the lumen and the balloon.

As to the Appellant's arguments that neither Dobak ‘171 nor Dobak ‘542 discloses a balloon expanded away from the shell and contracted towards the shell, the claim has not clearly set forth which portions of the wall the balloon or chamber is expanding towards and which wall it is expanding away from. As previously stated, sincethe balloon or chamber of Dobak‘171 nor Dobak ‘542 expands towards the top part of the shell wall and expanding away from the bottom part of the shell wall, Dobak‘171 nor Dobak ‘542 does in fact expand away from the shell. Furthermore, the balloon or chamber of both Dobak ‘171 and Dobak ‘542 is positioned adjacent to the wall when it is in a contracted state.

The Appellant’s argues that an aperture in the wall of an aorta or other artery would be harmful to the patient and is thus not disclosed by either Dobak‘171 or Dobak ‘542. However, in order to place the circulatory assist devices of both Dobak‘171 and Dobak ‘542, there would necessarily be and aperture in the vasculature. Therefore, both Dobak‘171 and Dobak ‘542 disclose an aperture in the aorta or other artery.

Furthermore, the Appellant argues that performance of a sternotomy or an aortotomy would be fundamentally different from both Dobak‘171 and Dobak ‘542. However, the examiner does not state that Dobak‘171 or Dobak ‘542 discloses either a a sternotomy or an aortotomy, but merely such a modification to the surgical procedures is well known and yields the predictable results of modifying therapy to meet specific patient needs.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections

are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The examiner merely relies on Lederman to disclose that it is well known to use a gas pressure source. Therefore, it would have been obvious to modify the fluid of Dobak'171 and Dobak '542 with the fluid of Lederman, since both fluids perform the same function of inflating and deflating the system.

Lastly, the Appellant argues that a partial extention around the full circumference of the stent lumen would be impossible for Dobak'171 and Dobak '542. However, the examiner restates that it would have been on obvious design modification since that Appellant specification has not set forth that a partial expansion provides an advantage, is used for a particular purpose, or solve a stated problem. Therefore, the partial expansion would be just as effective as the full expansion around the stent lumen.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment,

affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Alyssa M Alter/
Junior Examiner
Art Unit 3762

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/DONALD T HAJEC/

Director, Technology Center 3700

Conferees:

/Scott M. Getzow/

Primary Examiner, Art Unit 3762

/Carl H. Layno/

Supervisory Patent Examiner, Art Unit 3762 (acting) & 3766

(for Angela D Sykes

Supervisory Patent Examiner, Art Unit 3762)